

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

107501236

INTERNATIONAL APPLICATION NO.  
PCT/EP03/02269INTERNATIONAL FILING DATE  
6 March 2003PRIORITY DATE CLAIMED  
27 March 2002

## TITLE OF INVENTION

PHARMACEUTICAL FORMULATION FOR THE ACTIVE INGREDIENT BUDESONIDE

## APPLICANT(S) FOR DO/EO/US

Thomas BECKERT, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1.  This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2.  This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3.  This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4.  The US has been elected by the expiration of 19 months from the priority date (Article 31).
5.  A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a.  is attached hereto (required only if not communicated by the International Bureau).
  - b.  has been communicated by the International Bureau.
  - c.  is not required, as the application was filed in the United States Receiving Office (RO/US).
6.  An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a.  is attached hereto.
  - b.  has been previously submitted under 35 U.S.C. 154(d)(4).
7.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a.  are attached hereto (required only if not communicated by the International Bureau).
  - b.  have been communicated by the International Bureau.
  - c.  have not been made; however, the time limit for making such amendments has NOT expired.
  - d.  have not been made and will not be made.
8.  An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9.  An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10.  An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11.  A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12.  A copy of the International Search Report (PCT/ISA/210).

## Items 13 to 20 below concern document(s) or information included:

13.  An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14.  An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15.  A **FIRST** preliminary amendment.
16.  A **SECOND** or **SUBSEQUENT** preliminary amendment.
17.  A substitute specification.
18.  A change of power of attorney and/or address letter.
19.  A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20.  A second copy of the published international application under 35 U.S.C. 154(d)(4).
21.  A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22.  Express Mail Label No.
23.  Other items or information:

Application Data Sheet/Notice of Priority/PCT/IB/304/PCT/IB/308/PTO-1449/Cited References (3)

U.S. APPLICATION NO. (IF KNOWN) SEE 37 CFR  
107501236INTERNATIONAL APPLICATION NO.  
PCT/EP03/02269ATTORNEY'S DOCKET NUMBER  
253871US0PCT

24. The following fees are submitted.:

## BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

<input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO .....	\$1080.00
<input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO .....	\$920.00
<input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO .....	\$770.00
<input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) .....	\$730.00
<input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) .....	\$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =

\$920.00

Surcharge of \$130.00 for furnishing the oath or declaration later than  20  30 months from the earliest claimed priority date (37 CFR 1.492 (e)).

\$0.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	16 - 20 =	0	x \$18.00	\$0.00
Independent claims	1 - 3 =	0	x \$86.00	\$0.00
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	\$0.00
				<b>TOTAL OF ABOVE CALCULATIONS =</b>
				<b>\$920.00</b>
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$0.00
				<b>SUBTOTAL =</b>
				<b>\$920.00</b>
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).			+ <input type="checkbox"/>	\$0.00
				<b>TOTAL NATIONAL FEE =</b>
				<b>\$920.00</b>
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).		<input type="checkbox"/>		\$0.00
				<b>TOTAL FEES ENCLOSED =</b>
				<b>\$920.00</b>
				<b>Amount to be: \$</b>
				<b>refunded</b>
				<b>charged \$</b>

- A check in the amount of \_\_\_\_\_ to cover the above fees is enclosed.
- Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_ to cover the above fees.
- The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 15-0030
- Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

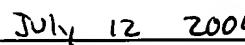
Surinder Sachar  
Registration No. 34,423
  
 SIGNATURE

Norman F. Oblon

NAME

24,618

REGISTRATION NUMBER

  
 DATE
CUSTOMER NUMBER  
22850

10/501236

0704 126 PCT/PCT 12 JUL 2004

Docket No. 253871US0PCT

IN RE APPLICATION OF: Thomas BECKERT, et al.

SERIAL NO: New U.S. PCT Application basedon PCT/EP03/02269

FILED: Herewith

FOR: PHARMACEUTICAL FORMULATION FOR THE ACTIVE INGREDIENT BUDESONIDE

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Transmitted herewith is an amendment in the above-identified application.

No additional fee is required

Small entity status of this application under 37 C.F.R. §1.9 and §1.27 is claimed.

Additional documents filed herewith: Credit Card Payment Form for \$920.00/PCT Transmittal Letter/Application Data Sheet  
Preliminary Amendment (with cover sheet)/Notice of Priority  
English Translation of Specification/Declaration/PCT/IB/304/PCT/IB/308  
Information Disclosure Statement/PTO-1449/Cited References (3)  
International Search Report

The Fee has been calculated as shown below:

CLAIMS	CLAIMS REMAINING		HIGHEST NUMBER PREVIOUSLY PAID	NO. EXTRA CLAIMS	RATE	CALCULATIONS
TOTAL	16	MINUS	20	0	x \$18 =	\$0.00
INDEPENDENT	1	MINUS	3	0	x \$86 =	\$0.00
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIMS					+ \$290 =	\$0.00
TOTAL OF ABOVE CALCULATIONS						\$0.00
<input type="checkbox"/> Reduction by 50% for filing by Small Entity						\$0.00
<input type="checkbox"/> Recordation of Assignment					+ \$40 =	\$0.00
TOTAL						\$0.00

A check in the amount of \$0.00 is attached.

Credit card payment form is attached to cover the fees in the amount of \$0.00

Please charge any additional Fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

If these papers are not considered timely filed by the Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. §1.136, and any additional fees required under 37 C.F.R. §1.136 for any necessary extension of time may be charged to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon
  
 Norman F. Oblon  
 Registration No. 24,618

Customer Number

22850

Tel. (703) 413-3000  
Fax. (703) 413-2220  
(OSMMN 05/03)Surinder Sachar  
Registration No. 34,423